

Message Text

UNCLASSIFIED

PAGE 01 STATE 151377
ORIGIN HEW-06

INFO OCT-01 ARA-14 EUR-12 EA-09 NEA-10 ISO-00 OES-07
EB-07 COME-00 SIG-02 /068 R

DRAFTED BY DHEW/FDA: J. R. WEINROTH, M.D.:CCK
APPROVED BY OES/APT/BMP: WJWALSH, III
DHEW/PHS/OASH/OIH: RFISCHER
EUR/EX:CREDMAN (INFO)
EA/EX:JCUNNINGHAM (INFO)
ARA/EX:GCHAFIN (INFO)
NEA?EX:EABINGTON (INFO)

-----129855 292013Z /63

P R 291825Z JUN 77

FM SECSTATE WASHDC

TO AMEMBASSY BERN PRIORITY

AMEMBASSY COPENHAGEN PRIORITY

AMEMBASSY LONDON PRIORITY

AMEMBASSY THE HAGUE PRIORITY

AMEMBASSY AMMAN PRIORITY

AMEMBASSY MEXICO PRIORITY

AMEMBASSY BOGOTA PRIORITY

AMCONSUL RIO DE JANEIRO PRIORITY

AMEMBASSY TOKYO PRIORITY

AMEMBASSY CANBERRA PRIORITY

AMEMBASSY WELLINGTON PRIORITY

AMEMBASSY SINGAPORE PRIORITY

AMEMBASSY REYKJAVIK PRIORITY

AMEMBASSY ATHENS PRIORITY

AMEMBASSY VIENNA PRIORITY

AMCONSUL MILAN PRIORITY

AMEMBASSY PARIS PRIORITY

AMEMBASSY ANKARA PRIORITY

AMEMBASSY BONN PRIORITY

AMEMBASSY HELSINKI PRIORITY

AMEMBASSY STOCKHOLM PRIORITY

AMEMBASSY MADRID PRIORITY

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AMEMBASSY TEL AVIV PRIORITY
AMEMBASSY TEHRAN PRIORITY
INFO AMEMBASSY BRASILIA
AMEMBASSY ROME

UNCLAS STATE 151377

E.O. 11652: N/A

TAGS: OGEN, ETRD, EIND, TBIO, XB, XF,XG, XU

SUBJECT: FDA ADVISORY - POTENTIAL FOR FAILURE OF
MEDICAL DEVICE("RECALL" T-II8-7)

1. FDA ADVISES OF THE FOLLOWING "RECALL":

PRODUCT INVOLVED:

"BENNETT MODEL AO-1 AIR-OXYGEN MIXER". PRODUCT IS USED
TO DELIVER A SPECIFIED AIR/OXYGEN MIXTURE (FROM 21-100
PERCENT OXYGEN).

PRODUCT IDENTIFICATION:

THE PRODUCT IS LABELED: "BENNETT AO-1 AIR-OXYGEN MIXTURE".

MANUFACTURER: BENNETT RESPIRATORY PRODUCTS, INC., SANTA
MONICA, CALIFORNIA.

RECALLING FIRM: PURITAN-BENNETT CORPORATION, OAK AT 13TH
STREET, KANSAS CITY, MISSOURI 64106.

2. REASON FOR RECALL RECOMMENDATION:
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THE FIRM'S OPERATING INSTRUCTIONS FOR THIS PRODUCT STATE
"CAUTION: WET COMPRESSED AIR MAY DAMAGE THE MIXER". IF
MOISTURE DAMAGE OCCURS, SOME OF THE FIRM'S ORIGINAL "AIR
REGULATOR SEAT MECHANISMS" JUST INSIDE THE AIR INTAKE
POINT HAVE FAILED, THUS ALLOWING AIR TO FLOW INTO THE
OXYGEN SIDE OF THE MIXER. THIS COULD RESULT IN A PATIENT
(INCLUDING INFANTS IN INCUBATORS) GETTING A REDUCED AMOUNT
OF OXYGEN (OTHER THAN THAT INDICATED ON THE MIXER). THUS,
A PATIENT COULD POTENTIALLY GET STRAIGHT AIR AND NO
OXYGEN (OTHER THAN THAT NORMALLY IN AIR).

3. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES
TO DETERMINE IF THEY HAVE RECEIVED THE FIRM'S LETTER
DATED 25 APRIL, 1977 WHICH IN ADDITION TO DEFINING THE
PROBLEM SUMMARIZES A VARIETY OF INSTRUCTIONS WHICH USERS
SHOULD ADHERE TO PRIOR TO UTILIZING THIS DEVICE. ANY
QUESTIONS CONSIGNEES MAY HAVE REGARDING THIS ADVISORY
SHOULD BE DIRECTED TO MR. J. J. WATERS, VICE PRESIDENT,
REGULATORY AFFAIRS, PURITAN-BENNETT CORPORATION, KANSAS
CITY, MO 64106.

4. FOREIGN CONSIGNEES AS FOLLOWS:

ING. RUEGGE AG
AUSTRASSE 19
CH-5430 WETTINGEN
SWITZERLAND

SIMONSEN AND WEELS
EFTF A/S
14 ROSKILDEVEJ
ALBERTSLUND, DENMARK

SIMONSEN AND WEEL LTD
HATHERLY HOUSE
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HATHERLY ROAD
SIDCUP DA14 4BR
KENT, U.K.

STOPLER INSTRUMENTEN AND
APPARATEN N.V.
P O BOX 2445
UTRECHT, HOLLAND

TAREQ SCIENTIFIC BUREAU
P O BOX 463
AMMAN, JORDAN

ESTABLECIMIENTOS
MEXICANOS COLLIERE SA
APARTADO NO. 114 BIS
MEXICO 22, D.F.

INSTITUTO ROOSEVELT
APTD O AEREO 35 35
BOTOTA, COLOMBIA

SOCIEDADE COMERCIAL PRO
MEDICO LTDA
RUA ITAPIRU 1292
RIO DE JANEIRO, BRAZIL

AMCO INCORPORATED
8-7-4-CHOME IIDABASHI
CHIYODA-KU
TOKYO, JAPAN

MEDISHIELD DIVISION
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COMMONWEALTH INDUSTRIAL GASES
P O BOX 81 BUNDOORA
SETTLEMENT RD BUNDOORA
VIC AUSTRALIA 3083

NEW ZEALAND INDUSTRIAL
GASES LTD
P O BOX 30-337
LOWER HUTT, NEW ZEALAND

SINGAPORE OXYGEN AIR
LIQUIDE PTE LTD
P O BOX 24I
16 JALAN BUROH JURONG
SINGAPORE 22

AUSTURBAKKI H F
P O BOX 1282
REYKJAVIK, ICELAND

PHARMACEUTICAL CO. LTD. MOHSEN SHALTCHILAR AND BROS.CO.
OMONIA SQUARE NORTH VILLA AVE
ATHENS, GREECE NO. 130

COMESA
SPITALGASSE
VIENNA IX AUSTRIA

COMESA S.P.A.
VIA FOGAZZARO 36
20135 MILAN
ITALY

COMPAGNIE FRANCAISE DE
PRODUITS OXYGENES
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154 RUE DE L UNIVERSITE
75007 PARIS FRANCE

KAZIM DEDEOGLU
SIRKECI DOGUBANK
IS HANI N.D. 113
ISTANBUL, TURKEY

CARL A. HOYER
PARIALLEE 44
28 BREMEN 1, GERMANY

INSTRUMENTARIUM OY
PL 357
00101 HELSINKI 10
FINLAND

LANDSTIGENS
INKIPSCENTRAL
S-171 83 SOLNA
STOCKHOLM, SWEDEN

MEDICINA Y ODONTOLOGIA
JOAQUIN GARCIA MORATO
133-TRIP
MADRID 3, SPAIN

MINISTRY OF HEALTH SUPPLY DIV.
STATE OF ISRAEL
P O B 7094
TEL-AVIV, ISRAEL VANCE

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NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01-Jan-1994 12:00:00 am
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: MEDICAL EQUIPMENT, RECALLS
Control Number: n/a
Copy: SINGLE
Sent Date: 29-Jun-1977 12:00:00 am
Decaption Date: 01-Jan-1960 12:00:00 am
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01-Jan-1960 12:00:00 am
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1977STATE151377
Document Source: CORE
Document Unique ID: 00
Drafter: J. R. WEINROTH, M.D.:CCK
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D770232-0893
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1977/newtext/t1977066/aaaaafew.tel
Line Count: 247
Litigation Code IDs:
Litigation Codes:
Litigation History:
Locator: TEXT ON-LINE, ON MICROFILM
Message ID: bbd6417d-c288-dd11-92da-001cc4696bcc
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 5
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 19-Oct-2004 12:00:00 am
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 2162208
Secure: OPEN
Status: NATIVE
Subject: FDA ADVISORY - POTENTIAL FOR FAILURE OF MEDICAL DEVICE("RECALL" T-II8-7)
TAGS: OGEN, ETRD, EIND, TBIO, XB, XF, XG, XU, FDA
To: BERN COPENHAGEN MULTIPLE
Type: TE
vdkgvwkey: odb://SAS/SAS.dbo.SAS_Docs/bbd6417d-c288-dd11-92da-001cc4696bcc
Review Markings:
Margaret P. Grafeld
Declassified/Released
US Department of State
EO Systematic Review
22 May 2009
Markings: Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 22 May 2009